



Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection

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Appendix A, Table 2. Antiretroviral Fixed-Dose Combination Tablets: Minimum Body Weights and Considerations for Use in Children and Adolescents (page 1 of 3)

This table may include recently approved FDCs that have not yet been added to individual drug sections in the [Pediatric Antiretroviral Drug Information Appendix](#) (see individual drug components for details).

General Considerations When Considering an FDC Tablet:

- For children weighing ≥ 25 kg, the Panel recommends using one of the following single-tablet, once-daily regimens: Triumeq (ABC/DTG/3TC), Genvoya (EVG/COBI/FTC/TAF), and Biktarvy (BIC/FTC/TAF).
- ABC and TAF are favored over ZDV because of lower risk of NRTI-associated mitochondrial toxicity.
- TDF is more potent than ABC at high viral loads when used in regimens that do not contain an INSTI.
- TAF is favored over TDF because of the lower risk of TDF-associated bone and renal toxicity.
- TDF is generally **not recommended** for children with SMR 1–3 because of TDF-associated bone toxicity; however, for a child weighing < 25 kg who can swallow pills, Truvada (FTC/TDF) low-strength tablets offer a reasonable, once daily combination alternative to twice daily ZDV plus 3TC or an alternative to ABC.
- RPV has low potency at high viral loads, a low barrier to resistance, and requires a high fat meal for optimal absorption, so EFV or an INSTI are favored.
- BIC and DTG, second-generation INSTIs, have a higher barrier to resistance than EVG and RAL, first-generation INSTIs.
- For images of most of the FDCs listed in this table, see the Antiretroviral Medications section of the [National HIV Curriculum](#). In addition, a [resource from the United Kingdom](#) illustrates the relative sizes of FDCs and individual ARVs (see the [Intro ARV Chart](#)). Although most of the drugs listed in that chart are the same as those in the United States, a few of the brand names are not the same as those listed in Appendix A, Table 2 below.
- FDCs and individual ARVs can also be looked up by drug (brand name and generic) at [DailyMed](#); size is listed under Ingredients and Appearance in the Product Characteristics section.

INSTI FDC Dosing for Children and Adolescents:

- [Elvitegravir](#):
 - Genvoya (EVG/COBI/FTC/TAF) is FDA approved for children and adolescents weighing ≥ 25 kg.
- [Dolutegravir](#):
 - The Panel recommends DTG 50 mg for children and adolescents weighing ≥ 20 kg, see the [dolutegravir](#) section. The FDA-approved dose is DTG 35 mg for patients weighing ≥ 30 kg to 40 kg, and DTG 50 mg for patients weighing ≥ 40 kg.
 - For children weighing ≥ 25 kg, DTG 50 mg can be given as Triumeq (ABC/DTG/3TC) in 1 large pill or as Descovy (FTC/TAF) plus DTG which requires 2 small pills.
 - Recent data identified a possible increased risk of NTDs among women who were receiving DTG at the time of conception. Specific recommendations about the initiation and use of DTG in adolescents and women of childbearing potential and in pregnant women are available in the Adult and Adolescent Antiretroviral Guidelines (See [Table 6b](#) and [Adolescents and Young Adults with HIV](#)) and in the

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Perinatal Guidelines (see [Teratogenicity](#) and [Recommendations for the Use of Antiretroviral Drugs in Pregnancy](#)).

- **Bictegravir:**

- Biktarvy (BIC/FTC/TAF) is now approved by the FDA for use in children and adolescents weighing ≥ 25 kg.

| FDC by Class Brand name and generic ^a products, when available | FDC Components | Minimum Body Weight (kg) or Age ^b | Pill Size (mm x mm) or Largest Dimension (mm) | Food Requirements |
|---|--|--|---|---------------------------|
| NRTI | | | | |
| Cimduo | 3TC 300 mg/TDF 300 mg | 35 kg | 19 | Take with or without food |
| Combivir and Generic 3TC/ZDV | 3TC 150 mg/ZDV 300 mg (scored tablet) | 30 kg | 18 x 7 | Take with or without food |
| Descovy | FTC 200 mg/TAF 25 mg | 25 kg: With INSTI or NNRTI 35 kg: With boosted PI | 12.5 x 6.4 | Take with or without food |
| Epzicom and Generic ABC/3TC | ABC 600 mg/3TC 300 mg | 25 kg | 21 x 9 | Take with or without food |
| Temixys | 3TC 300 mg/TDF 300 mg | 35 kg | N/A | Take with or without food |
| Trizivir and Generic ABC/3TC/ZDV | ABC 300 mg/3TC 150 mg/ZDV 300 mg | 40 kg (FDA) 30 kg (Panel) ^c | 21 x 10 | Take with or without food |
| Truvada | FTC 200 mg/TDF 300 mg | 35 kg | 19 x 8.5 | Take with or without food |
| Truvada Low Strength | FTC 167 mg/TDF 250 mg | 28 kg | 18 | Take with or without food |
| | FTC 133 mg/TDF 200 mg | 22 kg | 16 | Take with or without food |
| | FTC 100 mg/TDF 150 mg | 17 kg | 14 | Take with or without food |
| NRTI/NNRTI | | | | |
| Atripla | EFV 600 mg/FTC 200 mg/TDF 300 mg | 40 kg | 20 | Take on an empty stomach |
| Complera | FTC 200 mg/RPV 25 mg/TDF 300 mg | 35 kg and aged ≥ 12 years | 19 | Take on an empty stomach |
| Delstrigo | DOR 100 mg/3TC 300 mg/TDF 300 mg | Adults | 19 | Take with or without food |
| Odefsey | FTC 200 mg/RPV 25 mg/TAF 25 mg | 35 kg and aged ≥ 12 years | 15 | Take with a meal |
| Symfi | EFV 600 mg/3TC 300 mg/TDF 300 mg (scored tablet) | 40 kg | 23 | Take on an empty stomach |
| Symfi Lo | EFV 400 mg/3TC 300 mg/TDF 300 mg | 35 kg ^d | 21 | Take on an empty stomach |
| NRTI/INSTI | | | | |
| Biktarvy | BIC 50 mg/FTC 200 mg/TAF 25 mg | ≥ 25 kg | 15 x 8 | Take with or without food |

Appendix A, Table 2. Antiretroviral Fixed-Dose Combination Tablets: Minimum Body Weights and Considerations for Use in Children and Adolescents (page 3 of 3)

| FDC by Class Brand name and generic ^a products, when available | FDC Components | Minimum Body Weight (kg) or Age^b | Pill Size (mm x mm) or Largest Dimension (mm) | Food Requirements |
|--|---|---|--|----------------------------------|
| NRTI/INSTI, continued | | | | |
| Dovato | DTG 50 mg/3TC 300 mg | Adults | 19 | Take with or without food |
| Triumeq | ABC 600 mg/DTG 50 mg/3TC 300 mg | 40 kg (FDA) 25 kg (Panel) ^e | 22 x 11 | Take with or without food |
| NNRTI/INSTI | | | | |
| Juluca | DTG 50 mg/RPV 25 mg | Adults | 14 | Take with a meal |
| NRTI/INSTI/COBI | | | | |
| Genvoya | EVG 150 mg/COBI 150 mg/FTC 200 mg/TAF 10 mg | 25 kg | 19 x 8.5 | Take with food |
| Stribild | EVG 150 mg/COBI 150 mg/FTC 200 mg/TDF 300 mg | 35 kg | 20 | Take with food |
| NRTI/PI/COBI | | | | |
| Symtuza | DRV 800 mg/COBI 150 mg/FTC 200 mg/TAF 10 mg | Adults | 22 | Take with food |
| PI/COBI | | | | |
| Evotaz | ATV 300 mg/COBI 150 mg | 35 kg | 19 | Take with food |
| Prezcobix | DRV 800 mg/COBI 150 mg | 40 kg | 23 | Take with food |
| PI/RTV | | | | |
| Kaletra | <u>LPV/r Oral Solution:</u> • LPV 80 mg/mL and RTV 20 mg/mL <u>Tablets:</u> • LPV 200 mg/RTV 50 mg • LPV 100 mg/RTV 25 mg | <u>Post-Menstrual Age of 42 Weeks and a Postnatal Age of ≥14 Days:</u> • No minimum weight | 19 | Take with or without food |

^a Size or largest dimension of generic drugs are not listed because they may vary by manufacturer; this information is available by looking up one of the drug components using [DailyMed](#).

^b Minimum body weight and age are those recommended by the FDA unless otherwise noted.

^c Based on the current FDA-approved minimum body weights for Trizivir component drugs, the Panel suggests Trizivir may be used at a minimum body weight of ≥30 kg, although it is FDA approved for use in children and adolescents ≥40 kg. However, the Panel does not recommend regimens containing NRTI's only, or 3-NRTI regimens, for use in children.

^d Due to pharmacokinetic concerns, the Panel recommends caution when using Symfi Lo in children and adolescents who have a SMR 1-3 and weigh ≥40 kg, see the [efavirenz](#) section.

^e The Panel recommends using DTG 50 mg for children and adolescents weighing ≥20 kg based on available data. **However, the doses of ABC and 3TC in Triumeq are too high for children weighing <25 kg** (see the [dolutegravir](#) section).

Key to Abbreviations: 3TC = lamivudine; ABC = abacavir; ATV = atazanavir; ARV = antiretroviral; BIC = bictegravir; COBI = cobicistat; DRV = darunavir; DTG = dolutegravir; DOR = doravirine; EFV = efavirenz; EVG = elvitegravir; FDA = Food and Drug Administration; FDC = fixed-dose combination; FTC = emtricitabine; INSTI = integrase inhibitor; LPV = lopinavir; LPV/r = lopinavir/ritonavir; mm = millimetre; N/A = information not available; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside and nucleotide reverse transcriptase inhibitor; **NTD = neural tube defect**; RPV = rilpivirine; RTV = ritonavir; SMR = sexual maturity rating; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; ZDV = zidovudine